

## Substitute Specification – Clean Version

**WHAT IS CLAIMED IS:**

1. An apparatus for lancing the skin of a test subject, collecting a body fluid sample from the lanced site on the skin of the test subject, and holding the sample during an optical analysis of the sample to determine the concentration of an analyte in the sample, the apparatus comprising:

5 a body having an open end;

a hollow lancet having a polygonal cross section, the lancet having a tip adapted to puncture skin and to collect a body fluid sample, the lancet being substantially optically clear, the interior of the hollow lancet forming a capillary channel for moving a fluid sample from the tip to a reaction area including a reagent disposed along the interior of the hollow lancet;

10 a lancing mechanism disposed within the body, the lancing mechanism coupled to the lancet at an end of the lancet opposite the tip, the lancing mechanism being adapted to move the lancet between a retracted position, a lancing position for puncturing the skin of a test subject, and a collection position for collecting the body fluid sample;

15 an outer end cap having a first end coupled to the open end of the body and a second end for contacting the skin of the test subject, the outer end cap including an aperture formed therein that the tip of the lancet passes when in the lancing position; and

20 an inner end cap disposed within the outer end cap, the inner end cap having a first end coupled to the open end of the body and a second end having an aperture formed therein that the tip of the lancet passes when in the lancing position, the second end being adapted to contact the skin of the test subject when the lancet is in the collecting position.

25 2. The apparatus of claim 1 wherein the lancet is constructed of fused silica.

3. The apparatus of claim 1 wherein the lancet has a rectangular cross-section.

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4. The apparatus of claim 1 further comprising a vacuum member for evacuating air from the inner and outer end caps, the vacuum member being adapted to position the skin of the test subject against the second end of the inner end cap.

5 5. The apparatus of claim 4 wherein the vacuum member comprises a diaphragm.

6. The apparatus of claim 4 wherein the vacuum member comprises bellows.

7. The apparatus of claim 1 wherein the reagent disposed within the lance produces a colorimetric reaction indicative of the concentration of the analyte in the collected body fluid, the apparatus further comprising:

a light source for illuminating the reaction of the reagent and the analyte in the body fluid sample; and

a light detector for detecting light transmitted through the reaction.

8. The apparatus of claim 1 wherein the lancet has a square cross-section.

15 9. The apparatus of claim 1 wherein the retracted position and the collection position are substantially the same.

10. A method for lancing the skin of a test subject and collecting a produced body fluid sample from the lanced site on the skin of the test subject for determining the concentration of an analyte in the body fluid sample with a lancing and collection device, the lancing and collection device including a substantially optically clear, hollow lancet having a tip for puncturing skin, the method comprising the acts of:

25 placing an outer end cap of the device against the skin of a test subject;  
puncturing the skin with the lancet;  
positioning the punctured skin against an edge of an inner end cap of the device, the inner end cap being disposed within the outer end cap;

disposing the tip of the lancet a predetermined distance from the skin pulled against the edge of the inner end cap; and

30 collecting the body fluid sample from the puncture skin with the tip of the lancet.

11. The method of claim 10 wherein the hollow lancet includes a reaction area with a reagent adapted to produce a colorimetric reaction indicative of the

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analyte concentration in the sample, the method further comprising the acts of moving the collected body fluid sample from the tip of the lancet to the reaction area via capillary action.

12. The method of claim 11 wherein the analyte is glucose.

5 13. The method of claim 11 wherein the body fluid sample is blood.

14. The method of claim 11 further comprising the act of measuring the colorimetric reaction.

15. The method of claim 14 wherein the act of measuring further comprises the acts of:

10 illuminating the colorimetric reaction within the hollow, substantially clear lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

15 16. The method of claim 15 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

17. The method of claim 14 wherein the act of positioning further comprising the act of evacuating the air from the inner end cap with a vacuum member of the device.

20 18. A method for analyzing an analyte in a body fluid sample using a lancing device that includes a hollow lancet, the method comprising the acts of:

lancing the skin of a test subject with the hollow lancet, an interior of the hollow lancet forming a capillary channel;

25 collecting a body fluid sample from the lanced skin in the capillary channel of the hollow lancet; and

analyzing the body fluid sample for determining the analyte concentration in the body fluid sample while the collected body fluid sample remains in the lancet.

30 19. The method of claim 18 wherein the capillary channel of the hollow lancet has an inlet, and the act of collecting further comprises positioning the inlet of the capillary channel adjacent the lanced skin.

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20. The method of claim 18 wherein the lancing device includes an end cap, the method further comprising the act of positioning the skin against the end cap for maintaining the skin in a fixed position.

5 21. The method of claim 20 wherein the act of positioning further comprises the act of activating a vacuum member.

22. The method of claim 18 wherein the method further comprises the act of maintaining the skin in a fixed position while collecting the body fluid sample.

10 23. The method of claim 18 wherein the capillary channel contains a reagent for reacting with the analyte in the body fluid sample and producing a colorimetric reaction indicative of the concentration of the analyte in the body fluid sample.

24. The method of claim 23 wherein the act of analyzing further comprises the act of optically analyzing the body fluid sample.

15 25. The method of claim 24 wherein the act of optically analyzing comprises the acts of:

illuminating the colorimetric reaction within the hollow lancet with a light source; and

measuring the amount of light transmitted through the colorimetric reaction with a light detector.

20 26. The method of claim 25 further comprising the act of measuring the amount of light transmitted through the lancet to determine the start time of the colorimetric reaction.

27. The method of claim 18 wherein the hollow lancet is substantially optically clear.

25 28. The method of claim 27 wherein the hollow lancet has a polygonal cross section.

29. The method of claim 27 wherein the hollow lancet has a rectangular cross section.

30 30. The method of claim 27 wherein the hollow lancet has a square section cross section.

31. The method of claim 18 wherein the analyte is glucose.

32. The method of claim 18 wherein the body fluid sample is blood.